



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Request for Public Comment on Draft Health Center Program Compliance Manual

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Request for Public Comment on Draft Health Center Program Compliance Manual.

SUMMARY: HRSA is inviting public comment on the Draft Health Center Program Compliance Manual, hereafter referred to as the Compliance Manual. The purpose of the Compliance Manual is to provide a consolidated web-based resource to assist current and prospective health centers in understanding and demonstrating compliance with requirements of the Health Center Program, a HRSA-administered program authorized under 42 U.S.C. 254b. The Compliance Manual identifies requirements found in the Health Center Program's authorizing legislation and implementing regulations, as well as certain applicable grant regulations. The Compliance Manual also addresses HRSA's approach to determining eligibility for and oversight of the Health Center Program. In addition, the Compliance Manual includes the requirements for obtaining deemed Public Health Service (PHS) employee status under the Federally Supported Health Centers Assistance Acts of 1992 and 1995, for purposes of Federal

Tort Claims Act (FTCA) liability protections for the performance of medical, surgical, dental, and related functions within the scope of deemed PHS employment.

DATES: Submit written comments no later than November 22, 2016.

ADDRESSES: Written comments should be submitted through the HRSA/Bureau of Primary Health Care (BPHC) website at

<http://bphc.hrsa.gov/programrequirements/draftcompliancemanual/index.html>.

FOR FURTHER INFORMATION: For questions regarding this notice, contact HRSA/BPHC/Office of Policy and Program Development at HCPCComplianceManual@hrsa.gov.

SUPPLEMENTARY INFORMATION: HRSA provides grants to eligible applicants under section 330(e), (g), (h), and/or (i) of the PHS Act, as amended (42 U.S.C. 254b), to support the delivery of preventive and primary care services to medically underserved communities and vulnerable populations. Nearly 1,400 Health Center Program-funded health centers operate approximately 9,800 service delivery sites that provide care to over 24 million patients in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin. HRSA also designates eligible applicants under the Health Center Look-Alike Program (*see* Sections 1861(aa)(4)(B) and 1905(l)(2)(B) of the Social Security Act). Look-Alikes do not receive Health Center Program funding but must meet the Health Center Program statutory and regulatory requirements. Note that for the purposes of the Compliance Manual, the term “health

center” refers to entities that receive a federal award under section 330 of the PHS Act, as amended, subrecipients, and organizations designated as look-alikes, unless otherwise stated.

HRSA also makes determinations of deemed PHS employment status for health centers funded under section 330 and their covered individuals for purposes of providing liability protections under the Health Center Federal Tort Claims Act (FTCA) Program. Section 224(g)-(n) of the PHS Act (42 U.S.C. 233(g)-(n)) authorizes the FTCA Program and affords eligibility for FTCA coverage as the exclusive civil remedy for acts or omissions arising from the performance of medical, surgical, dental, or related functions within the scope of such employment by deemed health centers and by any officers, governing board members, employees, and certain individual contractors of these entities. A favorable FTCA deeming determination requires submission of an application by the Health Center Program awardee in the form and manner specified by HRSA.

The Compliance Manual includes sections identifying the requirements found in the Health Center Program’s authorizing legislation and program implementing regulations (section 330 of the PHS Act, as amended, 42 CFR Part 51c, and 42 CFR Part 56); certain applicable HHS grant regulations (45 CFR Part 75); and the Health Center FTCA Program’s authorizing legislation and implementing regulations (section 224(g)-(n) of the PHS Act, and 42 CFR Part 6).

Organizations receiving Health Center Program federal awards, including subrecipients, are also subject to all requirements incorporated within documents such as Funding Opportunity Announcements and Notices of Award. The Compliance Manual specifies Health Center

Program non-regulatory policy issuances that would be superseded, as well as those that would remain in effect.

The first chapter of the Compliance Manual outlines HRSA's approach to determining organizational eligibility for the Health Center Program, including how to demonstrate non-profit or public agency status. The chapter also describes organizational eligibility requirements that apply only to look-alikes. The second chapter clarifies HRSA/BPHC's oversight process by providing information on how HRSA will address areas of noncompliance and impose enforcement actions, including those for serious violations that may lead to the suspension of grant activities or termination of grant funding by HRSA under 45 CFR Part 75.

The Compliance Manual contains 18 chapters on Health Center Program requirements, each of which: a) cites the applicable statutory and regulatory authorities; b) lists statutory and regulatory requirements; c) describes how health centers would demonstrate compliance to HRSA; and d) includes examples of areas in which health centers have discretion or that may be helpful for health centers to consider when implementing the requirements.

The final chapter specifies the FTCA requirements for obtaining deemed PHS employment status, including how a health center would demonstrate compliance with the FTCA requirements in its annual deeming application. Please note that deemed employment status does not confer FTCA coverage in all cases, as health center providers also must comply with applicable legal eligibility requirements and covered actions must be undertaken within the scope of such deemed PHS employment (for more information, see the *Federal Tort Claims Act Health*

Center Policy Manual at <http://bphc.hrsa.gov/ftca/healthcenters/ftcahcpolicymanual.html>).

When FTCA matters become the subject of litigation, the U.S. Department of Justice and the federal courts may assume significant roles in certifying or determining whether or not a given activity falls within the scope of employment, for purposes of FTCA coverage.

Dated: August 30, 2016

James Macrae

Acting Administrator

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